

**REMARKS**

A. Period For Reply

A shortened statutory period for reply was set to expire three months from the mailing date of the Office Action of September 15, 2004. Three months from September 15, 2004 was December 15, 2004. January 15, 2005 falls on a Saturday. Monday, January 17, 2005 is Martin Luther King day, a federal holiday under 5 U.S.C. 6103(a). This Amendment and Remarks is being mailed with a certificate of mailing on or before Tuesday, January 18, 2005 (specifically on Sunday, January 16, 2005 at a 24/7/365 airport post office), along with a petition for an extension of time for one month.

B. Status

The Office Action of September 15, 2004 was nonfinal.

C. Disposition of Claims

Claims 21, 23, 26, 28-31, 33, and 35-46 are pending.

D. Application Papers

Approval of the formal drawings at the appropriate time would be appreciated. Formal drawings were filed with the filing of this case on December 12, 2003.

E. Priority under 35 U.S.C. §§ 119 and 120

This case claims the benefit under 35 U.S.C. 120 of U.S. Patent Application No. 09/452,656 filed December 1, 1999. An Application Data Sheet having such claim was filed with the filing of this case on December 12, 2003. Further, the Preliminary Amendment filed with the filing of this case on December 12, 2003 asked that the specification be amended to include such claim.

As to foreign priority, this case does not claim foreign

priority.

F. Attachments

Three PTO-1449 forms were filed with the filing of this case on December 12, 2003. All three of these forms were signed by the Patent Office and returned with the Office Action of September 15, 2004, and all of the references listed on such forms have been initialed. This is very much appreciated.

G. Basis for amendments to claims

Each of the independent claims in this case (claims 21, 26, 28, 33 and 36) has been amended from a one-piece envelope apart from said patch to a first side (such as a front, back, relatively thin, relatively thick, relatively rough, or relatively smooth side) being one-piece with a second side (such as a front, back, relatively thin, relatively thick, relatively rough, or relatively smooth side). Basis for such is found in the portions of the specification discussed below.

The implant 10 includes an envelope 12 with fill material 14. (Please see page 7, lines 1-19 and Figures 1A-D and 3A.) The envelope has at least two sides 16 and 20. (Please see page 7, lines 1-19 and Figures 1A-D and 3A.) Side 20 is the front side, includes a relatively smooth surface, and includes a relatively thin wall. (Please see page 7, lines 1-19 and Figures 1A-D and 3A.) Side 16 is the rear side, includes a relatively rough surface that engages tissue growth for restraining rotation by the breast implant and for orienting the relatively smooth front side to the front of the body, and is relatively thick. (Please see page 7, lines 1-19 and Figures 1A-D and 3A. Please also see page 4, lines 13-15.) The envelope as a whole is one piece (or one layer) such that the relatively thick rear side is one piece (or one layer) with the relatively thin front side. (Please see page 12, lines 17-24, describing that a four layer envelope is cured to a one layer envelope. Please also see

Figures 3A and 3B showing a relatively thick rear side that is one-piece and Figures 4A and 4B showing mandrel and dipping rods.)

Each of the independent claims in this case (claims 21, 26, 28, 33 and 36) has further been amended to change the limitation of "the envelope is sealed" to a limitation identical to or similar to --the envelope is sealable after being filled with fluid--. Basis for such includes page 12, lines 14-16, and page 14, lines 15-27, of the specification.

Basis for new dependent claims 37-41 includes the specification as a whole, including the drawings.

Basis for new dependent claims 42-46 is found at least on page 11, lines 15-23.

## H. The Office Action

### H.1. Double Patenting

On page 2 of the Office Action, claims 21-36 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,692,527. This rejection is respectfully traversed. However, applicant hereby files a terminal disclaimer in compliance with 37 CFR 1.321(c). The owner of the present application, U.S. Patent Application No. 10/734,876, is the owner of U.S. Patent No. 6,692,527 (U.S. Patent Application No. 09/452,656). Please see the Statement Under 37 CFR 3.73(b) filed with this case.

### H.2. Claim rejections - 35 USC § 112

On pages 2-3 of the Office Action, claims 21-36 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite because claims 21, 26, 28, 33 and 36 claim "said patch" which lacks antecedent basis. These claims have been amended to remove the phrase "said patch." It is therefore

respectfully that claims 21-36 are now in compliance with 35 U.S.C. 112, second paragraph.

H.3. Claim rejections - 35 USC § 102, the McGhan et al. reference

On pages 3-4 of the Office Action, claims 21-23 and 25-36 were rejected under 35 U.S.C. 102(b) as being anticipated by McGhan et al. (3,852,832). This rejection is respectfully traversed on the basis of applicant's discussion below.

Applicant has amended each of the independent claims to recite a first side being one-piece with a second side. Depending upon the claim that is being presented, each of such first and second sides have certain requirements such as being a front side, a rear side, a relatively thick side, a relatively thin side, a relatively rough side, and a relatively smooth side. Please see section G above.

In contrast, the McGhan et al. reference describes the following separate but joined elements:

- ◆ as one-piece, the envelope 12a;
- ◆ as a second piece, closure 12d;
- ◆ as a third piece, sheet 37;
- ◆ as a fourth piece, the cement between envelope 12a and closure 12d; and
- ◆ as a fifth piece, the cement between closure 12d and sheet 37.

It is respectfully submitted that the Patent Office cannot rely on the disclosure in McGhan et al. of the envelope 12a alone because this envelope 12a has the same thickness on its front side and rear side. To reject applicant's claims, the Patent Office is combining the first piece (the envelope 12a) with the second piece with the third piece with the fourth piece with the fifth piece.

Specifically, the McGhan et al. reference does not describe

the "one-piece" limitation. This limitation is found in each of independent claims 21, 26, 28, 33 and 36. This one-piece (or one layer) structure without additional pieces includes a relatively thin side, a relatively thick side, a relatively rough side, and a relatively smooth side, depending upon the claim that is presented.

In light of the above, it is respectfully submitted that claims 21-23 and 25-36 are not anticipated by the McGhan et al. reference.

H.4. Claim rejections - 35 USC § 102, the Baker reference

On page 4 of the Office Action, claims 28, 30, and 32 were rejected under 35 U.S.C. 102(b) as being anticipated by Baker (5,026,394). Of these claims, claim 32 has been canceled. This rejection is respectfully traversed on the basis of applicant's discussion below.

The Baker reference suffers from the same deficiency as does the McGhan et al. reference. This deficiency is that element 20 of Baker (the reinforcement member 20) is not one-piece with element 14 of Baker (the base portion 14 of the shell 12). Reinforcement member 20 and shell 12 are separate but joined elements. Specifically, three elements (the shell 12, the reinforcement member 20 and the raw silicone or silicone adhesive therebetween) are separate but joined elements.

Please see the paragraph bridging columns 2-3 of the Baker reference where Baker teaches that the shell opening facilitates installation of the reinforcement member by, for example, bonding the reinforcement member to the interior base portion of the shell and then turning the shell inside out. Such does not meet applicant's one-piece limitation.

It is noted that the Baker reference teaches that the reinforcement member 20 is adhered to the base portion 14 of the shell 12 by raw silicone or silicone adhesive. Please see column 4, lines 22-25 of the Baker reference. Such does not meet

applicant's one-piece limitation.

It is further noted that Baker indicates that the shell component and the reinforcement member can be formed as an integral unit. Please see column 6, lines 65-66 of the Baker reference. Such a disclosure, however, is not enabling because it does not teach how the shell component and the reinforcement member can be formed as an integral unit. Furthermore, even if the Baker reference is somehow enabling, such a disclosure cannot teach the claimed one-piece limitation pursuant to the Patent Office's own distinction between "integral" and "one-piece."

It is therefore respectfully submitted that claims 28 and 30 are not anticipated by the Baker reference.

H.5. Claim rejections - 35 USC § 103, the McGhan et al. reference

On pages 4-5 of the Office Action, claim 24 was rejected under 35 U.S.C. 103(a) as being unpatentable over McGhan et al. (3,852,832). This rejection is respectfully traversed. However, to limit issues for prosecution, claim 24 has been canceled.

H.6. Claim rejections - 35 USC § 103, the Prescott and Baker references

On pages 5-6 of the Office Action, claims 21-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prescott (5,522,896) in view of Baker (5,026,394). This rejection is respectfully traversed on the grounds of applicant's discussion below.

H.6.a. The Prescott breast prosthesis of Figure 1a

The Prescott breast prosthesis of Figure 1a comprises a biocompatible composite material dispersed through a matrix of elastomeric material. There is no teaching here of one side that is one-piece with another side being smooth relative to the other side or thick relative to the other side.

H.6.b. The Prescott breast prosthesis of Figure 1b

Where coating 4 is only on proximal side 6 of the breast prosthesis 2 shown in Figure 1b (as discussed by the Patent Office on page 5 of the Office Action), then such proximal side coating 4 is not one-piece with the other side of the Prescott prosthesis 2.

H.6.c. The Prescott breast prosthesis of Figure 1c

Where coating 4 is on both of the sides, as shown in Figure 1c of Prescott, then two things are true: 1) there is no teaching that one side is smooth relative to the other side; and 2) there is no teaching that one side is thick relative to the other side.

H.6.d. The Prescott reference teaches a prosthesis

The Prescott reference teaches a prosthesis. A prosthesis is an artificial device used to replace a missing body part, such as a limb, tooth, eye, or heart valve.

H.6.e. The Prescott prosthesis has a predetermined shape

The Prescott prosthesis comprises a biocompatible composite material having a predetermined shape. Please see column 4, lines 42-44 of the Prescott reference. The composite material can be provided to the physician previously molded, whereby the physician could trim or deform the molded composite material before or during positioning. Please see column 7, lines 21-24 of the Prescott reference. The composite material can be provided to the physician uncured, molded by the physician and subsequently cured either at room temperature or by addition of a catalyst. Please see column 7, lines 24-27 of the Prescott reference. Please note that different shapes of the Prescott figures: a breast prosthesis, a chin implant, a cheek augmentation device, an ossicular replacement prosthesis, middle

ear prosthesis, nasal prosthesis, and finger joint prosthesis.

H.6.f. The Prescott prosthesis, that may be open-cell, is not filled with fluid

The Prescott reference does not teach an implant that can be filled with fluid. The Prescott reference teaches an elastomeric material that may be in the form of an open-cell foam. Please see column 4, lines 57-58 of the Prescott reference. It is respectfully submitted that an open-cell cannot contain fluid. Even though Prescott teaches other materials, such as closed-cell foam, there is no teaching to contain fluid in such other materials.

Moreover, the Prescott reference does not teach an implant that can be filled with fluid to provide a three-dimensional shape. It is respectfully submitted that "a conventional silicone breast prosthesis" as described in column 5, line 60 of the Prescott reference does not teach a fluid filled implant.

H.6.g. It is respectfully submitted that there is no teaching or motivation for the combination of Prescott and Baker

It is respectfully submitted that there is no teaching or motivation for the combination of Prescott and Baker. Prescott teaches a prosthesis that cannot be filled with fluid. Baker teaches a fluid filled implant. The fixing of a dynamic (fluid filled) implant within a body is very different from the fixing of an essentially static prosthesis. Also, it is respectfully submitted that there is no teaching in Prescott that the "conventional implant of Prescott" is a fluid filled implant. Rather, it is respectfully submitted that the conventional implant of Prescott is a conventional prosthesis that is a soft but yet solid silicone prosthesis that is not fluid filled.

H.6.h. Even if the Prescott reference is combined with the Baker reference, such a combination does not teach the limitations of applicant's independent claims

The Prescott reference suffers from the same deficiency as do the McGhan et al. reference (discussed above) and the Baker reference (discussed above). This deficiency is that one cannot point to a one-piece envelope (or other like structure) in any of the Prescott or Baker references and, on such one-piece envelope, find a) a relatively thick side and a relatively thin side or 2) a relatively rough side and a relatively smooth side or 3) a relatively thick and rough side and a relatively smooth and thin side. Hence, even if the Prescott and Baker references are combined, such a combination cannot meet the limitations of any of the independent claims of applicant.

I. Information Disclosure Statement filed with present filing

It should be noted that an Information Disclosure Statement is being filed under the same cover with this Amendment and Remarks. This Information Disclosure Statement is accompanied by the fee (\$180) set forth in § 1.17(p).

The references listed on the attached PTO-1449 form were disclosed to applicant with the Office Action of December 8, 2004 of the related divisional case, U.S. Patent Application Number 10/462,278, on the Notice Of References Cited accompanying said Office Action. As to said Notice Of References Cited, the Quaid '744, the Yan et al. '425, the Baker '394, and the Prescott '896 are not enclosed because these references already have either been cited by either applicant or Patent Office in the present case. The remaining references are listed on the attached PTO-1449 form and these remaining references are: Teague '229, Howse '880, Redinger et al. '226, Ledergerber '338, Iversen et al. '275, Andrews et al. '220, and Hossainy et al. '793.

J. Summary

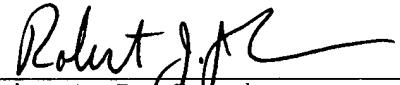
Applicant respectfully submits that the present application is in condition for allowance.

The references, individually or in combination, do not teach a first side (with front, back, relatively thin, relatively thick, relatively rough, or relatively smooth side claim requirements depending upon the claim presented) being one-piece with a second side (with front, back, relatively thin, relatively thick, relatively rough, or relatively smooth side claim requirements depending upon the claim presented).

The Examiner is respectfully invited to make contact with the undersigned by telephone if such would advance prosecution of this case.

Respectfully submitted,

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